REMARKS

Claims 1, 7, and 9 have been amended to affirmatively recite that the container contains a dose, and the subsidiary containers contain subsidiary doses.

The invention, as claimed in independent claims 1, 9 and 10, relates to a device and method that provides a single use inhaler with a subsidiary dose that is less than the first dose to permit a user to choose whether or not to use the subsididary dose with the primary dose to provide a variable dose.

Independent claim 1 stands rejected as anticipated by Gottenauer DE 44 00 084, which shows an inhaler with twenty-eight independently openable containers of medicament. In the office action it is stated that the containers are "fully capable of having different fractions or relative ratios of medicament contained within the different medicament containers." This statement is in error as a matter of law. Whether prior art is capable of something is irrelevant unless it discloses, teaches or at least suggests that feature. As noted in the MPEP 2143.03: "To establish prima facie obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art. In re Royka, 490 F.2d 981, 180 USPQ 580 (CCPA 1974)."

Here there is no disclosure, teaching or suggestion in Gottenauer of the claim limitation of the subsidiary dose being less than the primary dose, as is required by independent claim 1. Independent claims accordingly is not anticipated or rendered obvious by Gottenauer, and the independent claim 1 is allowable under 35 USC 103(a).

Independent claims 9 and 10 stand rejected as obvious under 35 USC 103(a) in view of Gottenauer DE 44 00 084 and Cheikh U.S. Patent No. 5,582,591.

Gottenauer DE 44 00 084 shows an inhaler with twenty-eight independently openable containers of medicament. Gottenauer does not teach or suggest a subsidiary dose being less than the primary dose.

Cheikh is cited for alleged disclosure of predetermined fractions of doses of one blister relative to another at col. 13, lines 30-40, which reads as follows:

> For insulin therapy, using a solid drug delivery device provides a clear advantage; patients have to carry only small caps or blister-packs of micro-

> syringe needles pre-loaded with different dosages of insulin (e.g., 10 IU, 20 IU, or 40 IU) and the small reusable delivery device. Without any preparation, the patient connects the pre-loaded needle of his choice to the device and can self-administer the proper dosage of insulin in a relatively painless fashion. The solid drug composition is stable for longer time at room temperature than any liquid formulation. (emphasis added).

Figs. 1A-1C show Cheikh's needles 1 preloaded with drugs 2, which are injected into a patient by attaching the needle to a syringe device with a micro plunger 4 that pushes the drugs 2 out of the needles. The patient simply picks the proper dosage, attaches the appropriate needle to the syringe, and injects the dosage. There is no disclosure or suggestion of combining doses, just selection of the needle with the desired dose. Moreover, even if the patient wanted to combine doses, he would need to first inject one dose from one needle, remove the needle, connect a new needle, and then inject the dose in it. There is nothing analogous to an inhalation channel which receives does from containers prior to inhalation.

If one were to apply Cheikh's teachings to Gottenauer, one would probably provide separate strips with blisters with different amounts of medicine, and attach the appropriate strip to the inhalation device.

The references, taken alone or in combination, nowhere disclose or suggest a single use inhaler provided with a subsidiary dose that is less than the first dose to permit a user to choose whether or not to use the subsididary dose with the primary dose to provide a variable dose.

The remaining claims depend on the independent claims and are allowable with them.

The claims have also been rejected for obviousness type double patenting on the basis of Kallstrand U.S. Patent No. 5,533,505. That patent only shows, and claims, a device with a single compartment. The claims herein require, in addition, a further compartment with a subsidiary dose that is less than the first dose to permit a user to choose whether or not to use the subsididary dose with the primary dose to provide a variable dose. This is nowhere suggested by the '505 patent, and the rejection should be withdrawn. This is more than the duplication of a known part for a known purpose, because it permits the user to make a decision and select a larger dose.

Attached is a marked-up version of the changes being made by the current amendment.

Applicant asks that all claims be allowed. Enclosed is a $920 check for the Petition for Extension of Time fee. Please apply any other charges or credits to Deposit Account No. 06-1050.

Respectfully submitted,

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Version with markings to show changes made

In the claims:

Claim 1, 7 and 9 have been amended as follows:

1. (Three Times Amended) A single use inhaler for administering medicament by inhalation, the inhaler comprising:

an inhalation channel through which a user may inhale;

a first container [for] containing a first dose of medicament; and

a first release means for releasing said first dose into the said inhalation channel; wherein the inhaler further comprises:

at least one subsidiary container [for] containing a subsidiary dose of medicament;

at least one respective subsidiary release means for releasing said subsidiary dose into said inhalation channel; wherein

said first release means is independently operable of said at least one subsidiary release means such that one or more of said first dose and said subsidiary dose may be released into said inhalation channel at the same time and such that a variable dose is provided and the subsidiary dose of said at least one said subsidiary container is a predetermined fraction of said first dose that is less than said first dose.

7. (Three Times Amended) An inhaler according to claim 1 wherein the inhaler comprises at least two subsidiary containers containing further subsidiary doses and the further subsidiary doses of each of said at least two subsidiary containers is a predetermined fraction of said first dose that is less than said first dose.

9. (Three Times Amended) A method of providing a variable dose in a single use inhaler having an inhalation channel through which a user may inhale, a first container [for] containing a first dose of medicament and a first release means for releasing said first dose into said inhalation channel, said method comprising;

providing at least one subsidiary container in said single use container [for] containing a subsidiary dose of medicament whereby the subsidiary dose of said at least one said subsidiary container is a predetermined fraction of said first dose that is less than said first dose;

providing at least one respective subsidiary release means for releasing said subsidiary dose of medicament into said inhalation channel; and

arranging for said first release means to be independently operable of said subsidiary release means such that one or both of said first dose and said subsidiary dose may be released into said inhalation channel at the same time and such that a variable dose is provided.